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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,875	08/31/2006	Benjamin L. Miller	176/61752	7925
26774	7590	02/05/2009	EXAMINER	
NIXON PEABODY LLP - PATENT GROUP 1100 CLINTON SQUARE ROCHESTER, NY 14604				WHISENANT, ETHAN C
ART UNIT		PAPER NUMBER		
1634				
MAIL DATE		DELIVERY MODE		
02/05/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/584,875	MILLER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ethan Whisenant	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 31 October 2006.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-17 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 04 November 2008 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/2/2006 ; 4/26/2007; 2/20/2008; and 7/22/2008</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |



**NON-FINAL ACTION**

1. The applicant's Preliminary Amendment filed 31 OCT 06 has been entered.  
Following the entry of the Preliminary Amendment, **Claim(s) 1-17** is/are pending.

**SEQUENCE RULES**

2. This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

**35 USC § 112- 2nd Paragraph**

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH**

4. **Claim(s) 1-17** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Claim 1** is indefinite because it is unclear to the examiner exactly what is intended by the phrase "in the absence of the other nucleotides of the target nucleic acid sequence". Would not the structure/Free energy value of a "single hairpin" of for example Figure 3 (see the hairpin labeled Hairpin X in the Appendix ) be substantially the same in the presence or absence of the other nucleotides of the target nucleic acid sequence. Note that the Figure of the appendix is taken from Zuker et al. [Nucleic Acids Research 9(1) : 133-148 (1981)]. Could not the entire 459 nucleotide fragment shown

in be termed a hairpin, thus there would be no excess nucleotides (i.e. other nucleotides of the target nucleic acid sequence).

**Claim 1** is indefinite because there is no nexus between the preamble and the claim steps. Claim 1 in its preamble direct to a method which is to accomplish a particular goal. However, none of the claim steps states that this goal is accomplished. For clarity, claimed methods should recite that the purpose of the method has been attained (i.e. provide a nexus between the preamble and the claim steps).

**Claim 8** is indefinite because the phrase “the method of preparing a molecular beacon ” lacks proper antecedent basis.

## 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.  
or
- (d) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

### **CLAIM REJECTIONS UNDER 35 USC § 102**

**6.** **Claim(s) 1-3** is/are rejected under 35 U.S.C. 102(b) as being anticipated by Zuker et al. [Nucleic Acids Research 9(1) : 133-148 (1981)].

Zuker et al. teach a method of identifying hairpin nucleic acid probes which comprises all of the limitations recited in **Claim 1-3**. For this reading note that the hairpin oligonucleotide molecule (probe) of, for example, Figure 3 comprises 459 nucleotides, all of which are involved in the formation of the hairpin oligonucleotide molecule so the limitation which reads in the absence of the other nucleotides of the target nucleic acid sequence are moot. Also note that the hairpin molecule of Figure 3 has a predicted E value of -181.4 kcal/mol (i.e. at most about -3 kcal/mol).

### **CONCLUSION**

**7.** **Claim(s) 1-17** is/are rejected and/or objected to for the reason(s) set forth above.

**8.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM - 5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

/Ethan Whisenant/  
Primary Examiner  
Art Unit 1634

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